SAFETY DATA SHEETS

This SDS packet was issued with item:

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N/A

AMPHASTAR PHARMACEUTICALS, INC.
11570 SIXTH STEET, RANCHO CUCAMONGA, CALIFORNIA 91730
TELEPHONE (800) 423-4136 FAX (909) 980-8296

MATERIAL SAFETY DATA SHEET

SECTION I. MATERIAL IDENTIFICATION

Identity/Material Name:	CORTROSYN® (cosyntropin) for Injection (as a Diagnostic Agent)
Stock Number:	5900
Unit Size:	0.25 mg Cortrosyn® (lyophilized powder for reconstitution in 1 mL 0.9% Sodium Chloride Injection USP), single dose vial
Manufacture's Name:	Amphastar Pharmaceuticals, Inc. Telephone: (800)423-4136
Address:	11570 Sixth Street, Rancho Cucamonga, California 91730 Fax: (909)980-8296

SECTION II. HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

Ingredient Name:	Amount per mL:	Permissible Exposure Level:
Cosyntropin USP	0.25 mg	Unknown
Glacial Acetic Acid USP	as needed	Unknown
Sodium Hydroxide NF	as needed	Unknown
Mannitol USP	10 mg	Unknown
Sodium Chloride USP	9 mg	Unknown
Water for Injection USP	QS Ad	N/A

SECTION III. PHYSICAL/CHEMICAL DATA

Boiling Point (°C):	N/A	Melting Point (°C):	Unknown
Viscosity:	N/A	Vapor Pressure:	N/A
Specific Gravity:	Unknown	Percentage Volatile:	N/A
Vapor Density:	Unknown	Evaporation:	Water solvent will slowly evaporate
Solubility in Water:	Solution miscible with water		
Appearance and Odor:	White lyophilized powder. After reconstitution: clear, colorless, odorless solution.		

SECTION IV. FIRE AND EXPLOSION DATA

Flash Point:	Unknown	Flammable Limits:	LEL N/A	UEL	N/A
Extinguishing Media:	Water, carbon dioxide, dry chemical or foam.				
Special Fire Procedures:	Unknown				
Stability:	Stable under ordinary conditions of use and storage. Protection from light and freezing. Reconstituted Cortrosyn® (cosyntropin) for injection should not be retained.				
Approved By:	RA/ [signature]	Date Prepared:	7/22/03		

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SECTION V. REACTIVITY DATA	
Conditions to Avoid:	Temperature out side of 15 – 30°C (59 – 86°F), freezing, and light exposure. Injection is discolored or contains a precipitate.
Incompatibility (Materials to Avoid):	Unknown
Hazardous Decomposition Products:	Unknown

SECTION VI. HEALTH HAZARDS DATA	
LD_{50}	Unknown
Pregnancy and Lactation:	*Pregnancy Category C* Animal reproduction studies have not been conducted with CORTROSYN® (cosyntropin) for Injection. It is also hot known whether CORTROSYN® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CORTROSYN ® should be given to a pregnant woman only if clearly needed. It is not known whether this drug is excreted in human milk, Because many drugs are excreted in human milk, caution should be exercised when CORTROSYN® (cosyntropin) for Injection is administered to a nursing woman.
Carcinogenesis, Mutagenesis, Impairment of Fertility:	Long term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential or impairment of fertility. A study in rats noted inhibition of reproductive function like natural ACTH.
Effect and Treatment of Overdosage:	Since CORTROSYN® (cosyntropin) for Injection is intended for diagnostic and not therapeutic use, adverse reactions other than a rare hypersensitivity reaction are not anticipated. A rare hypersensitivity reaction usually associated with a pre-existing allergic disease and/or a previous reaction to natural ACTH is possible. Symptoms may include slight whealing with splotchy erythema at the injection site. There have been rare reports of anaphylactic reaction. The following adverse reactions have been reported in patients after the administration of CORTROSYN® and the association has been neither confirmed nor refuted: • bradycardia • tachycardia • hypertension • peripheral edema • rash.
Eye Contact:	Flush eyes immediately with copious amounts of water. Seek medical attention if deemed necessary.
Inhalation:	Do not inhale the lyophilized Cosyntropin USP powder. May cause hypersensitivity reaction. Remove to fresh air. Get medical attention for any breathing difficulty.
Skin Irritation:	Avoid direct skin contact. Wash affected skin surfaces immediately with mild soap and copious amounts of water.
Accidental Ingestion:	If large amounts were swallowed, give water to drink and get medical advice.

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SECTION VI. HEALTH HAZARDS DATA (CONTINUED)

Systemic:

Cosyntropin is α 1 - 24 corticotropin, a synthetic subunit of ACTH. It is an open chain polypeptide containing, from the N terminus, the first 24 of the 39 amino acids of natural ACTH. The sequence of amino acids in the 1 - 24 compound is as follows:

Ser - Tyr - Ser - Met - Glu - His - Phe - Arg - Trp - Gly - Lys - Pro - Val - Gly - Lys - Lys - Arg - Arg - Pro - Val - Lys - Val - Tyr - Pro

CORTROSYN® (cosyntropin) for Injection is intended for use as a diagnostic agent in the screening of patients presumed to have adrenocortical insufficiency. Because of its rapid effect on the adrenal cortex it may be utilized to perform a 30-minute test of adrenal function (plasma cortisol response) as an office or outpatient procedure, using only 2 venipunctures.

CORTROSYN® (cosyntropin) for Injection exhibits the full corticosteroidogenic activity of natural ACTH. The pharmacologic profile of CORTROSYN® is similar to that of purified natural ACTH. It has been established that 0.25 mg of CORTROSYN® will stimulate the adrenal cortex maximally and to the same extent as 25 units of natural ACTH. This dose of CORTROSYN® will produce maximal secretion of 17-OH corticosteroids, 17- ketosteroids amd /or 17 - ketogenic steroids.

The extra-adrenal effects which natural ACTH and CORTROSYN® have in common include increased melanotropic activity, increased growth hormone secretion and an adipokinetic effect. These are considered to be without physiological or clinical significance. This property of CORTROSYN® assumes added importance in view of the known antigenicity of natural ACTH.

The only contraindication to CORTROSYN® (cosyntropin) for Injection is a history of a previous adverse reaction to it.

CORTROSYN® (cosyntropin) for Injection exhibits slight immunologic activity, does not contain animal protein and is therefore less risky to use than natural ACTH. Patients known to be sensitized to natural ACTH with markedly positive skin tests will, with few exceptions, react negatively when tested intradermally with CORTROSYN®. Most patients with a history of a previous hypersensitivity reaction to natural ACTH or a pre-existing allergic disease will tolerate CORTROSYN®. Despite this however, CORTROSYN® is not completely devoid of immunologic activity and hypersensitivity reactions including rare anaphylaxis are possible. Therefore, the physician should be prepared, prior to injection, to treat any possible acute hypersensitivity reaction. Corticotropin may accentuate the electrolyte loss associated with diuretic therapy.

SECTION VII. PRECAUTIONS FOR SAFE HANDLING AND USE

Precautions:	Once the unit is opened and used, any remaining portion must be discarded with the entire unit. DO NOT retain reconstituted Cortrosyn® (cosyntropin) for Injection.
Steps to be Taken if Released or Spilled:	Absorb onto paper. Wash spill site with copious amounts of water.
Waste Disposal:	Approved chemical waste incineration or approved aqueous discharge to municipal or on-site wastewater treatment systems.

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SECTION VIII. CONTROL MEASURES	
Respiratory Protection:	N/A
Ventilation:	Local ventilation adequate.
Skin Protection:	Adequate skin protection recommended including gloves.
Eye Protection:	Adequate eye protection recommended including safety glasses.
Approved By: RA/ [signature]	Date Prepared: 7/22/03

Rx Only. Refer to package insert for additional information.

The information contained herein is believed to be complete and accurate. However, it is the user's responsibility to determine the suitability of the information for their particular purpose. International Medication Systems, Limited assumes no additional liability or responsibility resulting from the usage of, or reliance on this information.

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